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August 9, 2022

The Honorable Maryellen Noreika
United States District Court
for the District of Delaware
844 North King Street
Room 4324, Unit 19
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *Jazz Pharms., Inc., et al. v. Avadel CNS Pharms., LLC*
C.A. Nos. 21-691, 21-1138 & 21-1594 (MN)

Dear Judge Noreika:

This firm, together with Quinn Emanuel, represents Plaintiffs (“Jazz”) in these matters. We write pursuant to Local Rule 3.1(b) to provide an update to the Court on actions related to these matters. On October 19, 2021, this Court denied Defendant Avadel’s motion to secure expedited judgment on its Orange Book delisting counterclaim related to U.S. Patent 8,731,963 (the “’963 Patent”). D.I. 55, 56.

Despite its outstanding request to resurrect that motion in this Court (D.I. 117), Avadel recently sought relief in another forum. On July 21, 2022, Avadel filed a complaint in the District of District Columbia against the FDA, seeking relief under the Administrative Procedure Act related to Jazz’s listing of the ’963 Patent in the Orange Book, and the FDA’s related determination that Avadel must certify against that patent in connection with its 505(b)(2) New Drug Application. *See Avadel CNS Pharmaceuticals, LLC v. Becerra, et al.*, C.A. No. 22-2159, D.I. 1 (D.D.C.) Avadel likewise sought expedited relief in the D.C. court, filing a concurrent motion for a preliminary injunction with its complaint. *Id.* at D.I. 2. In that motion, Avadel has taken positions regarding the scope of the ’963 Patent’s claims, whether the ’963 Patent is appropriately listed in the Orange Book, the scope of Jazz’s listing code for that patent, and how Avadel’s accused product compares to that information. *See id.*

On July 27, Jazz moved to intervene in the D.C. action, which the court granted on July 28. *Id.* at D.I. 18. The D.C. court also scheduled briefing (to take place on August 19, September 2, and September 14), and a hearing for September 30, 2022, to address Avadel’s request for a preliminary injunction.

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There is significant overlap between issues that Avadel has presented to both this Court and the D.C. court in regards to, among other things, Avadel's delisting counterclaim. Counsel for Jazz are available if the Court has any questions, including about the potential impact the D.C. litigation will have on this case.

Respectfully,

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)

JAT/lo

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via CM/ECF and e-mail)